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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,716	11/16/2005	Henrik Leisner	P70568US0	8936

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EXAMINER	
ANDERSON, CATHARINE L	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,716	LEISNER, HENRIK	
	Examiner	Art Unit	
	Lynne Anderson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 18 June 2008 have been fully considered but they are not persuasive.

2. In response to the applicant's argument that Holmberg does not teach a difference in tensile strength between the two flanges, it is noted that Holmberg teaches an ostomy attachment appliance designed to perform the same function as the claimed invention (i.e. is configured for removable adhesive connection to the coupling element), and therefore optimizing the tensile strengths of the flanges would be obvious.

3. Applicant's arguments with respect to Nielsen have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmberg (5,496,296) in view of Steer (4,890,608).

6. With respect to claims 1, 6-7, 9, 13-14, and 18, Holmberg discloses all aspects of the claimed invention with the exception of a further flexible layer. Holmberg also remains silent as to the relative tensile strengths of the first and second flanges. Holmberg discloses an ostomy device, as shown in figure 2, comprising a collection bag

11 and a base plate 12. The base plate 12 has an opening 32 and a first flange 27. The first flange 27 is connected to a coupling element on the collection bag 11, the coupling element comprising a second flange 17 and a layer of adhesive 19.

7. Holmberg teaches that the first flange 27 is relatively stiff to allow the user to brace the first flange during separation of the ostomy bag from the base plate, as disclosed in column 4, lines 25-39. Holmberg teaches the desire for the first flange to be stiff but remains silent as to the tensile strength of the first flange relative to the second flange. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the device of Holmberg with a first flange having a greater tensile strength than the second flange, since Holmberg teaches the desire for the first flange to be stiff and strong so that it may be used as a brace during separation of the ostomy bag from the base plate.

8. Steer discloses an ostomy device having a collection bag and a base plate, the base plate having a first flange 20, as shown in figure 2. Steer teaches a further flexible layer 34 having a layer of adhesive 32 for placement on the outer surface of the first flange, as shown in figure 2. The adhesive strength of adhesive 32 is less than the yield strength of the flexible layer 34, allowing the flexible layer 34 to be removed from the first flange 20 during removal of the collection bag to indicate the number of bags used and to provide a fresh adhesive layer for attachment of the next bag, as disclosed in column 4, lines 29-41 and 54-66.

9. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the ostomy device of Holmberg with the further flexible layer taught

by Steer to indicate the number of bags used and to provide a fresh adhesive layer for attachment of the next bag.

10. With respect to claims 2-3, 11, and 15-16, Holmberg remains silent as to the connecting strength and the yield strength between the flexible layer and the flanges. Holmberg teaches the desire for only the first flange to remain attached to the base plate when the ostomy bag is separated, to permit a series of bags to be attached to the base plate without having to replace the base plate, as disclosed in column 2, lines 48-52. To allow for the removal of the ostomy bag without removal of the base plate at the same time, it would be obvious to one of ordinary skill in the art at the time of invention to provide the device with a connection strength between the flexible layer and the second flange than exceeds the adhesive strength, so that the adhesive releases the flexible layer and second flange, thereby allowing the ostomy bag comprising the second flange to be removed from the base plate. Likewise, it would have been obvious for the yield strength of the flexible layer to have the same order of magnitude as the first flange, to allow the flexible layer and the first flange to be separated, so the ostomy bag may be removed without removal of the base plate comprising the first flange.

11. With respect to claims 4, 8, 12, 17, and 19, Holmberg remains silent as to the elastic modulus of the flexible layer and the flanges. Holmberg teaches the need for the first flange to be more resilient during deformation than the second flange, as shown in figure 4. In order to provide a material having a greater resiliency, it would be obvious to one of ordinary skill in the art at the time of invention to provide the flange of

Holmberg with a greater elastic modulus so as to allow for a resilient, deformable flange.

12. With respect to claim 5, Nielsen teaches an adhesive layer 9 provided on the flexible layer 8 for affixing the flexible layer 8 to the base plate and providing extra security against leaks, as described in column 5, lines 36-41. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the flexible layer with an adhesive layer, as taught by Nielsen, for affixing the flexible layer to the base plate and providing extra security against leaks.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. A./
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761